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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT

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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,872	Applicant(s) GIRON ET AL.	
	Examiner CHRISTIAN JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-74, 78-96, 103, 104 and 110-121 is/are pending in the application.
- 4a) Of the above claim(s) 110-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-74, 78-96, 103, 104, 120 and 121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 5, 2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 66-69, 71-74, 78-84, 86-89, 91, 95, 96, 104, and 120-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) in view of Baghdassarian (US 2003/0050567), and further in view of Guilluy (USP #5,711,306).

4. As to claim 66, Lemelson teaches a system for collecting a plurality of samples of breath of a subject (Abs) comprising: a breath conduit adapted to convey breath from the subject (11); a sensor for determining a characteristic of said breath exhaled from the subject (28), a plurality of sample containers for collection of said plurality of samples (20); a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (column 5, lines 30-35).

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Lemelson fails to teach a sample distributor which directs the samples according to the sensed characteristics of said exhaled breath as well as a pump for collecting the exhaled breath by means of a suction effect. However, Baghdassarian, in a breath collection system, teaches that the activation of the collection process can be made to activate according a signal from a carbon dioxide sensor ([0048]). As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson with a collection activation setup taught by Baghdassarian so that sample collection can be made only when necessary. The combined teachings of Lemelson and Baghdassarian fail to teach a pump for collecting said exhaled breath from the subject. Guilluy, in a device for directing a sample of expired air from a subject (Abs), teaches the use of a pump (13) which may be used in conjunction with the subject blowing into the cannula to fill up a sample container (col. 2 lines 34-41). When the samples are collected into sample containers, the sample containers are not empty at all but contain air. To fill these containers with the sample breaths would require displacement of the air that is already contained within the container. The use of a pump as taught by Guilluy would both aid in collecting the exhaled breath by means of a suction (or negative pressure) effect by displacing the ambient air already in the containers and thus creating this suction effect. Without the aid of a pump, it would require the subject to blow and thus pressurize the tube to displace the ambient air, which would may be difficult for a patient to do effectively. As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by

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Lemelson incorporating a collection activation setup taught by Baghdassarian with a pump as taught by Guilluy to aid in the collection of sample breaths.

5. As to claim 67, Lemelson teaches a controller, where said different samples of said exhaled breath are directed to different ones of said plurality of sample containers according to said controller (column 5, 32-35).

6. As to claim 68, Lemelson discloses the invention substantially as claimed. Lemelson does not teach a sample distributor which is operated manually. However, Lemelson does disclose an automatic sample distributor and it would not be beyond the ability of one of ordinary skill in the art to utilize a manually operated sample distributor when the end result is equivalent.

7. As to claim 69, Lemelson teaches a system according to claim 66 wherein said sample distributor directs said samples at predetermined times (column 7, lines 47-52).

8. As to claim 71, Lemelson teaches the predetermined times are determined by a characteristic of said breath of the subject (column 7, lines 17-21).

9. As to claim 72, Lemelson teaches the characteristic of said breath is at least one of the carbon dioxide concentration, the oxygen concentration, the excess pressure, the temperature, the humidity, the flow rate and the sound of said breaths (column 6, line 65 to column 7, line 4).

10. As to claim 73, Lemelson teaches the predetermined times are determined by at least one physiological characteristic of the subject (column 6, lines 14-17).

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11. As to claim 74, Lemelson teaches the at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (column 6, lines 14-17).

12. As to claim 78, Lemelson, once combined with Baghdassarian, teaches a valving system to select at least part of said breath for transfer to said sample distributor, according to said carbon dioxide levels (column 5, lines 39-42).

13. As to claim 79, Lemelson, once combined with Baghdassarian, teaches a valving system to select at least part of said breath for transfer to said sample distributor, according to said characteristic of said breath (column 5, lines 39-42).

14. As to claims 80-83, Baghdassarian teaches the sensor is a capnographic analyzer and carbon dioxide levels comprises carbon dioxide concentrations, waveforms, or both ([0048]) and the collection is determined when the concentration is at a plateau value such that alveolar air is sampled ([0047]; Fig. 4).

15. As to claim 84, Lemelson teaches the controller causes said sample distributor to direct said samples at predetermined times (column 7, lines 47-52).

16. As to claim 86, Lemelson teaches the predetermined times are determined by a characteristic of said breaths of the subject (column 7, lines 17-21).

17. As to claim 87, Baghdassarian teaches the characteristic of said breath is at least one of CO₂ concentration, O₂ concentration, excess pressure, temperature, humidity, flow rate, and sound of said breaths ([0048]).

18. As to claim 88, Lemelson teaches the predetermined times are determined by a physiological characteristic of the subject (column 7, lines 16-21).

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19. As to claim 89, Lemelson teaches the at least one physiological characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, blood pressure, pulse rate, gastric pH value and temperature (column 6, lines 14-17).

20. As to claim 91, Lemelson teaches at least one of said sample containers has rigid walls and is evacuated before collection of said samples (column 2, lines 39-46). Although Lemelson does not specify a container with rigid walls, the use of a technique to controllably flush and clean residual gas is indicative of a container that has not started out deflated, and thus has the rigidity to sustain an internal volume or space.

21. As to claim 95, Lemelson teaches a system for collecting a plurality of samples of breath of a subject comprising: a breath conduit adapted to convey breath from the subject (11); a valving system (col 5, lines 39-42); a plurality of sample containers for collection of said plurality of samples (20); and a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (col 5, 30-35). Lemelson teaches a controller causing said sample distributor to direct said different predetermined samples to said different ones of said plurality of sample containers (74). Lemelson fails to teach a valving system which directs the samples according to the sensed characteristics of said exhaled breath and a pump for collecting said breath. However, Baghdassarian, in a breath collection system, teaches that the activation of the collection process can be made to activate only when carbon dioxide levels are within acceptable ranges ([0048]). Although Baghdassarian fails to specifically mention a capnographic analyzer, it teaches the

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monitoring of carbon dioxide levels in real time, which is the definition of a capnograph.

As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson with a collection activation setup taught by Baghdassarian so that sample collection can be made only when necessary. The combined teachings of Lemelson and Baghdassarian fail to teach a pump for collecting said exhaled breath from the subject. Guilluy, in a device for directing a sample of expired air from a subject (Abs), teaches the use of a pump (13) which may be used in conjunction with the subject blowing into the cannula to fill up a sample container (col. 2 lines 34-41). The use of a pump as taught by Guilluy would both aid in collecting the exhaled breath by means of a suction (or negative pressure) effect by displacing the ambient air already in the containers and thus creating this suction effect. Without the aid of a pump, it would require the subject to blow and thus pressurize the tube to displace the ambient air, which may be difficult for a patient to do effectively. As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson incorporating a collection activation setup taught by Baghdassarian with a pump as taught by Guilluy to aid in the collection of sample breaths.

22. As to claim 96, Lemelson teaches the at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (col 6, lines 14-17).

23. As to claim 104, Lemelson teaches at least one of said sample containers has rigid walls and is evacuated before collection of said samples (col 2, lines 39-46).

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24. As to claim 120, Lemelson teaches that the samples are adapted to be analyzed in one or more breath tests (col. 2 lines 33-52).

25. As to claim 121, Lemelson teaches one or more breath tests comprising the determination of bacterial overgrowth (col. 26-36).

26. Claims 70 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Baghdassarian (US 2003/0050567), and Guilluy (USP #5,711,306) as applied to claims 69 and 84 above, and further in view of Ben-Oren et al. (USP #6,656,127).

27. As to claims 70 and 85, Lemelson discloses the invention substantially as claimed. Lemelson does not teach that the predetermined times are at fixed time intervals. However, Ben-Oren teaches a breath analysis apparatus for sample collection or analysis that discloses collection at a fixed time, such as every half hour (col. 6 lines 28-50). The collection at fixed time intervals enables ease of comparison between samples, and easily shows progression of the patient according to a fixed spacing timeline. As such, it would have been obvious to one of ordinary skill in the art to modify the combined teachings of Lemelson, Baghdassarian, and Guilluy with the collection and analysis of samples during fixed time intervals as taught by Ben-Oren to show steady progression of patient breath parameters in instances where the change in progression would require significant time to be reflected in the measurements.

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28. Claims 90 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Baghdassarian (US 2003/0050567), and Guilluy (USP #5,711,306) as applied to claims 66 and 95 above, and further in view of Opekun, Jr. et al. (USP #5,140,993).

29. As to claims 90 and 103, Lemelson, Baghdassarian, and Guilluy disclose the invention substantially as claimed. However, Lemelson and Baghdassarian do not disclose a sample container in the form of a flexible bag. Opekun teaches a flexible, inflatable plastic bag (Abs) for the purpose of collecting a breath sample. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson having a collection activation setup taught by Baghdassarian and the pump of Guilluy with an inflatable plastic bag as taught by Opekun which would allow the means for collection to be kept to a minimal volume prior to deployment.

30. Claims 92 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Baghdassarian (US 2003/0050567), and Guilluy (USP #5,711,306) as applied to claim 80 above, and further in view of Daniels et al. (USP #6,099,481).

31. As to claim 92, Lemelson, Baghdassarian, and Guilluy disclose the invention substantially as claimed. However, Lemelson and Baghdassarian do not disclose a valving system adapted to direct breath exhaled when said CO₂ concentration is at the plateau into one of said containers and breath inhaled when said CO₂ concentration is

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at the baseline into a second one of said sample containers. Daniels teaches respiratory measurements which includes carbon dioxide elimination, airway dead space, and physiologic dead space which clearly shows the plateau during exhalation and the baseline for inhalation for the purpose of deciphering the volume of CO₂ elimination and alveolar volume (col 8 line 61 to col 9 line 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the breath collection device taught by Lemelson incorporating a collection activation setup taught by Baghdassarian, and the pump of Guilluy with capturing of breath samples during these baseline and plateau periods in order to enable to machine to decipher such physiological parameters as CO₂ elimination and alveolar volume as taught by Daniels.

32. As to claim 94, Lemelson, Baghdassarian, Guilluy, and Daniels disclose the invention substantially as claimed. Lemelson teaches that said predetermined gas is a volatile organic compound. Although Lemelson does not explicitly state the phrase “volatile organic compound”, the examiner notes that there is no limiting definition within the applicant’s disclosure as to the limitations of the phrase. Thus, the examiner is taking the broadest reasonable definition of the phrase, in light of the disclosure, wherein “volatile organic compound” may mean any substance detectable from human expired breath that has high enough vapor pressure to vaporize into a gaseous form. Since Lemelson discloses that his teachings can be used to automatically analyze the chemical contents within the breath of living beings for analysis of a variety of conditions and diseases of said living being, the examiner regards Lemelson to teach the limitations of the claim.

33. Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Baghdassarian (US 2003/0050567), Guilluy (USP #5,711,306), and Daniels et al. (USP #6,099,481) as applied to claim 92 above, and further in view of Kenny et al. (USP #5,042,501).

34. As to claim 93, Lemelson, Baghdassarian, Guilluy, and Daniels disclose the invention substantially as claimed. Lemelson teaches sample containers which absorb a predetermined gas of said breath of the subject (col 6, lines 37-43). Lemelson, Baghdassarian, and Daniels fail to teach a heater for expelling said predetermined gas of said breath of the subject. However, Lemelson recognizes the importance of cleaning out the chambers, utilizing a water trap and flushing mechanism to clean out the chambers (Fig. 2, 29). Kenny teaches a breath analysis device which utilizes a heating means (170) to flush the system with zero air (col. 3 lines 35-65). While Kenny does not utilize this system in a collection container, one of ordinary skill would recognize that such a system could also be readily applied to Lemelson's teachings to clean out the chambers. As such, it would have been obvious to one of ordinary skill in the art to modify the combined teachings of Lemelson, Baghdassarian, Guilluy, and Daniels with the heating means of Kenny to further aid in expelling the collected samples from the container thereby allowing for containers to be reused in further collections and analysis.

Response to Arguments

35. Applicant's arguments with respect to claims 66 and 95 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Thurs (10-9:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. J./
Examiner, Art Unit 3735
6/17/10

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